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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,681	05/10/2001	Alexander James Wigmore	2001-0878.ORI	7056

7590 10/31/2003

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	15

DATE MAILED: 10/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/831,681	WIGMORE, ALEXANDER JAMES	
	Examin r	Art Unit	
	Susan Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-5,7-9,16,30 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-9,16,30 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time and Request for Continued Examination filed 08/18/03.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/18/03 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-9, 16, 30, and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that applicant's specification does not provide support for the limitation "at least 80% of the chromone

dissolves within 5 minutes" recited in lines 4-5 of claim 1. The word "at least" set a lower limit of the chromone dissolves to 80%, wherein applicant's specification discloses the lower limit can be as little as 15% (page 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7-9, 16, 30, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watts et al. US 6,200,602.

Watts teaches a composition for enhanced uptake of polar drugs, including sodium cromoglycate, from the colon (see abstract, column 5, lines 33-35). The composition also comprise dispersing agent (surfactant) having HLB value between 1-20 (column 4, lines 20 through column 2, lines 1-4). The composition further comprises excipient, such as Avicel™ (microcrystalline cellulose), and can be formulated into capsule, tablet or pellets (column 6, lines 16-20). The dosage form can be coated to ensure that the tablet or pellet does not break-up and release the drug until it reaches the proximal colon (column 6, lines 21 through column 7, lines 1-27).

Watts does not teach the dissolve rates of the dosage form. However, Watts teaches the use of similar coating material (enteric coating), which only begin to dissolve when the dosage form entered the small intestine (column 6, lines 45-48).

"When the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established". *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Therefore, it is the position of the examiner that the enteric coated tablet or pellet of Watts would have similar dissolve rates desired by the applicant. Accordingly, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable dissolve rate to obtain the claimed invention, because Watts teaches the advantageous results in the use of similar enteric-coated dosage form to ensure the release of drug in the small intestine.

It is noted that Watts does not teach the diameter size of the pellets. However, Watts teaches similar dosage form, *e.g.*, enteric-coated pellets useful to deliver drug to the proximal colon (id). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Thus, it is the position of the examiner that the diameter size of the pellets would have been obvious to one of the skilled artisan.

Although Watts teaches the use of microcrystalline cellulose, Watts is silent as to the amounts being used. However, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or

workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 1-5, 7-9, 16, 30, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wigmore GB 2 324 962 A.

Wigmore teaches an oral sodium cromoglycate formulation for bio-availability to the small intestine (see abstract). The formulation further comprises excipient, *e.g.*, microcrystalline cellulose (page 10, lines 13-15). Wigmore also teaches that the formulation can be in tablet dosage form (page 12, lines 26-29). Wigmore also teaches that not more than 10% of the total sodium cromoglycate is released after two hours in simulated gastric fluid, and at least about 90%, preferably 100% of the total sodium cromoglycate is released within two hours (page 6).

Wigmore does not teach the release rate at 5 minutes, however, Wigmore teaches that sodium cromoglycate is released in the small intestine at 10 minutes. Thus, one of ordinary skill in the art having the teaching of Wigmore would have been motivated to determine suitable release rate at 5 minutes after the dosage form reached the intestine, because release rate is a parameter that is routinely determine by formulation chemist. Wigmore teaches the use of the same active drug, *e.g.*, sodium cromoglycate, in the same dosage form, *e.g.*, tablet for bio-availability to the small intestine, for the same treatment, namely, treatment of allergic conditions.

With regarding to the weight ratio of the disintegrant to the active drug, it would have been obvious for one of ordinary skill in the art to, by routine experimentation

determine suitable amount of disintegrant to obtain the desired release rate. Furthermore, it is noted that not all disintegrant would exhibit the same release rate. Therefore, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

Applicant's arguments filed 05/29/03 have been fully considered but they are not persuasive.

Applicant's Declaration filed 05/29/03 has been fully considered but is not persuasive, because the Declaration is not in commensurate with the claims. Declaration shows the claimed release rate can be achieved by using microcrystalline cellulose in a tablet form. Applicant's generic claim does not require the disintegrant to be microcrystalline cellulose, nor tablet dosage form.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-

5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600